UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff

v.

ACTAVIS LLC, TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Defendants.

Civil Action No. 1:17-cv-982

COMPLAINT

Plaintiff Eli Lilly and Company ("Lilly"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Actavis LLC, on behalf of Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Defendants") of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell its Pemetrexed Injection Concentrate, 25mg/ml (500 mg/20ml, 1000mg/40ml) products ("Defendants' NDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Defendants notified Lilly that it had submitted to the FDA NDA No. 208419 for Defendants' NDA Products by letter dated February 21, 2017 ("Defendants' Notice Letter" or "Notice Letter"). Upon information and belief, Actavis' NDA Products will be marketed as competing products to ALIMTA®, a

chemotherapy agent developed and distributed by Lilly and used for the treatment of various types of cancer.

PARTIES

2. Lilly is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Upon information and belief, Actavis LLC ("Actavis") is a corporation organized and existing under the laws of the State of Delaware having a place of business at 400 Interpace Pkwy, Parsippany, New Jersey 07054. Upon information and belief, Actavis is a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.

4. Upon information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454 USA. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

5. Upon information and belief, Teva Pharmaceutical Industries, Ltd. ("TPI") is a corporation organized and existing under the laws of Israel, having a place of business at 5 Basel Street, Petach Tikva 49131, Israel.

6. Upon information and belief, Actavis' preparation and submission of NDA No. 208419 was done at the direction, under the control, and for the direct benefit of Teva USA, and/or TPI. Upon information and belief Teva USA, and/or TPI directed Actavis to submit NDA No. 208419.

7. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of NDA No. 208419, Defendants will act in

concert to distribute and sell the generic product described in NDA No. 208419 throughout the United States and within Indiana.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. Defendants are subject to personal jurisdiction in Indiana because, among other things, they regularly transact and/or solicit business in Indiana and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here.

11. Upon information and belief, Actavis, Teva USA, and/or TPI regularly do business in Indiana and have engaged in a persistent course of conduct within Indiana by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Indiana, and/or by directly selling pharmaceutical products in Indiana. Actavis, Teva USA, and/or TPI have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

12. Upon information and belief, Actavis LLC was acquired by TPI on August 3, 2016. The TPI website has a separate page for "Actavis Integration." The Actavis website is now on Teva letterhead, and just provides contact information for TPI and Teva USA and points to their respective websites. In its 2016 20-F filing to the SEC, TPI reported on the acquisition of Actavis and the potential risks it posed to TPI's business. In part, TPI told the SEC: "The acquisition significantly expanded our generics product portfolio and pipeline, R&D capabilities and global operational network," "Our strong legacy generics business, combined with the Actavis Generics business, has a world-leading product portfolio, comprehensive R&D capabilities, robust product pipeline and an efficient global operational network. The combined

generic business has a wide-reaching commercial presence, as the market leader in the United States … .” Under the section devoted to their United States business, TPI reported “We are the leading generic drug company in the United States. We market over 500 generic products in more than 2,000 dosage strengths and packaging sizes, including oral, injectable and inhaled products. … We seek to continue our U.S. market leadership based on our ability to introduce new generic equivalents for brand-name products on a timely basis … including through our recent acquisition of Actavis Generics, which has substantially expanded our generics operations and pipeline.”

13. Upon information and belief, Actavis, Teva USA, and TPI operate as an integrated, unitary generic pharmaceutical business. Teva USA’s website connects its history to the funding of TPI and states that it “is a proud part of Israeli-based [TPI],” and directs visitors to the global TPI website for more information. TPI and Teva USA are divided into a number of business units, including the “Generics” segment. Upon information and belief, Actavis is part of this “Generics” segment.

14. Upon information and belief, Defendants have sought approval in NDA No. 208419 to distribute its NDA Products in the United States, including in Indiana (and in this District), and will do so upon approval of NDA No. 208419. The filing of NDA No. 208419 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Indiana and this District, and reliably indicates plans to engage in marketing of Defendants’ NDA Products in this State and District.

15. Upon information and belief, with knowledge of the processes described in the FDCA and the Hatch-Waxman Act, Defendants directed their Notice Letter to Lilly, an entity incorporated in Indiana, at its corporate headquarters in Indiana, and alleged in the Notice Letter

the invalidity, unenforceability, and/or non-infringement of Lilly's '209 patent. Upon information and belief, Defendants deliberately challenged Lilly's patent rights, and knew when they did so that they were triggering a forty-five-day period for Lilly to bring an action for patent infringement under the FDCA. Moreover, upon information and belief, Defendants knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana. Teva USA was already involved in litigation over the '209 patent with Lilly in this District and did not challenge personal jurisdiction in that suit.

16. Because Lilly is incorporated and has its principal place of business in Indiana, the injury and consequences of Defendants' filing of NDA No. 208419, challenging Lilly's patent rights, are suffered in Indiana. Upon information and belief, Defendants knew that they were deliberately challenging the patent rights of an Indiana entity and seeking to challenge intellectual property held in Indiana and that the effects of any successful challenge of the '209 patent would be felt by Lilly in Indiana.

17. Upon information and belief, Defendants derive substantial revenue from pharmaceutical products that are used and/or consumed within Indiana, and which are manufactured by Actavis, Teva USA, TPI, or its affiliates and/or for which Actavis, Teva USA, or TPI is the named applicant on approved NDAs or ANDAs. Upon information and belief, various products for which Actavis, Teva USA, TPI, or its affiliates, is the named applicant on approved NDAs and ANDAs are available at pharmacies in Indiana.

18. Upon information and belief, if NDA No. 208419 is approved, Defendants' NDA Products, under the direction and control of physicians practicing in Indiana, will be administered to patients of Indiana. These activities, as well as Defendants' marketing, selling, and/or distributing of Defendants' NDA Products, would have a substantial effect within Indiana

and would constitute infringement of Lilly's patent in the event that Defendants' NDA Products are approved before the '209 patent expires.

19. For the reasons described above, among others, the filing of NDA No. 208419 was suit-related conduct with a substantial connection to Indiana and this District, the exercise of personal jurisdiction in this Court does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Defendants.

BACKGROUND

20. ALIMTA® is indicated (in combination with cisplatin) (a) for the treatment of patients with malignant pleural mesothelioma, or (b) for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer. ALIMTA® also is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. ALIMTA® also is indicated for maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

21. Lilly sells ALIMTA® in the United States pursuant to a New Drug Application that has been approved by the FDA.

22. The '209 patent, titled "Antifolate Combination Therapies," was duly and legally issued on August 10, 2010. The '209 patent is attached as Exhibit A hereto.

23. Lilly is the assignee of the '209 patent.

24. An actual case or controversy exists between Lilly and Actavis with respect to infringement of the '209 patent.

25. This action is being filed within 45 days of Lilly's receipt of Actavis' Notice Letter.

26. Lilly has previously sued Teva USA in this Court for infringement of the '209 patent. In the litigation that followed, Teva USA challenged both infringement and validity of the '209 patent. The Court made findings of fact and conclusions of law against Teva USA and for Lilly with respect to both infringement and validity and entered final judgment in favor of Lilly. Teva USA is collaterally estopped from challenging the validity of any claim of the '209 patent that was adjudicated in the prior litigation. Teva USA is also collaterally estopped from contesting infringement under any theory that was adjudicated in the prior litigation.

27. Actavis and TPI are in privity with Teva USA. Actavis and TPI are also collaterally estopped from challenging the validity of any claim of the '209 patent that was adjudicated in the prior litigation. Actavis and TPI are also collaterally estopped from contesting infringement under any theory that was adjudicated in the prior litigation.

COUNT I
(Infringement of U.S. Patent No. 7,772,209)

28. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

29. Upon information and belief, Defendants' NDA Products contain pemetrexed disodium or its equivalent.

30. Upon information and belief, the proposed labeling for Defendants' NDA Products involves administration of folic acid and vitamins B_{12}.

31. Upon information and belief, the use of Defendants' NDA Products in accordance with and as directed by Defendants' proposed labeling for those products will infringe claims 1-22 of the '209 patent, either literally or under the doctrine of equivalents.

32. Upon information and belief, Defendants filed as part of NDA No. 208419 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C.

§ 355(b)(2)(A)(iv), asserting that the claims of the '209 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Defendants' NDA Products.

33. The purpose of NDA No. 208419 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants' NDA Products prior to the expiration of the '209 patent.

34. Defendants' submission of NDA No. 208419 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants' NDA Products prior to the expiration of the '209 patent is an act of infringement of the '209 patent under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 208419, *i.e.*, prior to the expiration of the '209 patent.

36. Upon information and belief, Defendants have knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 208419.

37. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '209 patent when their NDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

38. Upon information and belief, Defendants know that Defendants' NDA Products are especially made or adapted for use in infringing the '209 patent, and that Defendants' NDA

Products are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of NDA No. 208419.

39. The foregoing actions by Defendants constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

40. Unless Defendants are enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

* * *

WHEREFORE, Lilly requests the following relief:

(a) A judgment that Defendants have infringed the '209 patent and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of the '209 patent;

(b) A judgment ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Defendants' NDA Products, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Defendants, and all persons acting in concert with Defendants, from making, using, selling, offering for sale, marketing, distributing, or importing Defendants' NDA Products, or any product the use of which infringes the '209 patent, or the inducement of or contribution to any of the foregoing,

prior to the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Defendants' NDA Products, or any product the use of which infringes the '209 patent, prior to the expiration date of the '209 patent, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by other of the '209 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Lilly's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

/s/ Anne N. DePrez

Anne DePrez (No. 4728-49)
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204
Telephone: (317) 236-1313
FAX: (317) 231-7433
Email: Anne.DePrez@btlaw.com

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Dov P. Grossman
David M. Krinsky
Galina I. Fomenkova
Alec T. Swafford
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
Telephone: (202) 434-5000

Attorneys for Plaintiff Eli Lilly and Company